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SYNEYE.002A (formerly QLT.002A)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Legerton et al.) Group Art Unit 2873
Appl. No. :	10/657,061)
Filed :	September 5, 2003)
For :	HYBRID CONTACT LENS SYSTEM AND METHOD)
Examiner :	Jessica T. Stultz)
)
)

DECLARATION OF JOSEPH T. BARR PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Joseph T. Barr, declare and state as follows:

1. I am a United States citizen and I reside at 2212 Gnarled Pine Drive, Dublin, OH 43016.

2. I am currently a Professor at Ohio State University. I've been a professor for fifteen years and affiliated with the University for at least twenty-two years. I am also Associate Dean for Clinical Services and Professional Programs, and Director of the NEI-sponsored Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Photography Reading Center. I also served as Chief of the Contact Lens Clinical Service at Ohio State from 1983 to 1988. Prior to this, I worked at Dow Corning for three years, where, among other projects, I worked on the development of the silicon elastomer lens. While at Dow Corning, I was the director of clinical and material research.

3. I hold a Doctor of Optometry, a Master's Degree in Physiological Optics, and a Residency Certificate from Ohio State University.

4. I am the immediate past Chair of the American Academy of Optometry Cornea and Contact Lens Section. Since 1977, I have been a member of the American Optometric Association

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(AOA) and a member of the International Society of Contact Lens Research. Since 1990, I have been a member of the International Association of Contact Lens Educators. Since 1983, I have been a member of the Association of Optometric Contact Lens Educators.

5. Since 1988 I have been Editor of the professional journal *Contact Lens Spectrum*, which publishes articles on advances in contact lens design, manufacturing methods, materials and fitting. I have knowledge of research, successful and failed contact lens designs, and the commercialization of contact lens designs over the past twenty years.

6. I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve contact lenses and/or the cornea.

7. I have worked in the contact lens industry for the past twenty-eight years, including the research and development of contact lens designs, including hybrid contact lenses, materials, and solutions. Further, I've been involved in research related to the SoftPerm hybrid contact lens, and worked with the corneal reaction of hybrid contact lenses. I also have knowledge of hybrid contact lens designs that have been commercialized. The commercially available SoftPerm hybrid contact lens had a low Dk center (Dk of about 12) and low Dk peripheral skirt (Dk of about 5). I understand that one major problem with the SoftPerm lens is that it delaminated at the junction between the hard center and the soft skirt. It is my understanding that the SoftPerm lens continues to have tearing problems. The SoftPerm lens is the only commercially available hybrid contact lens.

8. I have reviewed the pending claims in the above-identified application and the proposed amendment to the claims filed herewith. I have also reviewed U.S. Patent No. 6,043,328 ("Domschke") and GB Patent No. 1,417,650 ("Sohnges"), the two references I understand the Examiner has used to reject pending claims in the above-identified application as being obvious. I disagree that these claims are obvious in view of Domschke and Sohnges.

9. In my opinion, the combination of Domschke and Sohnges would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

10. Domschke does not disclose, teach or suggest a hybrid contact lens with a substantially rigid central portion having a Dk of at least 30×10^{-11} (cm^2/sec) (mL O_2)/($\text{mL} \times \text{mm Hg}$) and substantially flexible hydrophilic peripheral or annular portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid

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central portion. Instead, Domschke describes a polysiloxane-polyol macromer material, and contact lenses including said material. Domschke also discloses coating a surface of a lens with a hydrophilic material to improve the hydrophilicity of the lens. Indeed, there is no disclosure or suggestion in Domschke to provide a hydrophilic peripheral skirt, or bond a hydrophilic peripheral skirt to a rigid central portion. Domschke's single reference to a hybrid lens appears to refer to either (a) a lens with a rigid core section and a hydrophilic surface, (b) a rigid gas permeable lens with very high flexure, or (c) a soft lens made of a Silicon Elastomer (aka Silicon rubber) with no water content, all of which have been referred to at times in the contact lens industry as hybrid lenses because they exhibited some characteristics found in both soft and rigid gas permeable lenses (e.g., intermediate rigidity between that of a rigid gas permeable lens and that of a soft lens). However, none of these contact lenses (i.e., a lens with a rigid core section and a hydrophilic surface, a rigid gas permeable lens with very high flexure, or a soft lens with no water content) teach or suggest a contact lens having a substantially rigid central portion coupled to a substantially flexible hydrophilic peripheral portion, as recited in the amended claims of the above-identified application.

11. With respect to Sohnges, the reference does not disclose a hybrid contact having a hard central portion with a Dk of at least 30×10^{-11} . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high Dk central portion, 2) provide a hydrophilic skirt, or 3) bonding a high Dk central portion to a hydrophilic skirt in any manner. Therefore, one of skill in the art looking at these two references would not be able to combine the material of Domschke with the lens in Sohnges to obtain the claimed invention.

12. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision,

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movement of the lens occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lens with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture a wider lens, which experiences less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of a hard lens.

13. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high Dk providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as 1988 of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

14. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past twenty-eight years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Domschke and Sohnges.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: 1/29/06


Joseph T. Barr, OD, M.S.

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